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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-64, CMS-10295, CMS-10302 and CMS-10185]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Revision of a currently approved collection.

Title of Information Collection: Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program. Use: Form CMS-64 has been used since January 1980 by Medicaid state agencies to report their actual program benefit costs and administrative expenses. CMS uses this information to compute the federal financial participation for the state's Medicaid program costs. Certain schedules of the CMS-64 form are used by states to report budget, expenditure and related statistical information required for implementation of the Medicaid portion of the State

Children's Health Insurance Programs, Title XXI of the Social Security Act, established by the Balanced Budget Act of 1997. Form Number: CMS-64 (OCN: 0938-0067). Frequency: Quarterly. Affected Public: State, Local, or Tribal Governments. Number of Respondents: 56. Total Annual Responses: 224. Total Annual Hours: 16,464. (For policy questions regarding this collection contact Abraham John at 410-786-4518. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Revision of a currently approved collection. Title of Information Collection: Reporting Requirements for States Under Transitional Medical Assistance (TMA) Provisions. Use: The HHS Secretary is required to submit annual reports to Congress with information collected from states in accordance with section 5004(d) of the American Recovery and Reinvestment Act of 2009. Medicaid agencies in 50 states complete the reports while CMS reviews the information to determine if each state has met all of the reporting requirements specified under section 5004(d). We are revising this package to remove the requirement to report the Medicaid Federal Medical Assistance Percentage since it no longer needs to be collected from states. Form Number: CMS-10295 (OCN: 0938-1073). Frequency: Quarterly. Affected Public: State, Local, or Tribal Governments. Number of Respondents: 50. Total Annual Responses: 200. Total Annual Hours: 400. (For policy questions regarding this collection contact Rhonda Simms at 410-786-1200. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen Use: Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended Section 1861(t)(2)(B) of the Social Security Act (42 U.S.C.

1395x(t)(2)(B)) by adding at the end the following new sentence: ‘On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.’ We believe that the implementation of this statutory provision that compendia have a “publicly transparent process for evaluating therapies and for identifying potential conflicts of interests” is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. Form Number: CMS–10302 (OCN: 0938–1078); Frequency: Reporting, Recordkeeping and Third-party disclosure; Affected Public: Business and other for-profits and Not-for-profit institutions; Number of Respondents: 845; Total Annual Responses: 900; Total Annual Hours: 5,135. (For policy questions regarding this collection contact Brijet Coachman at 410-786-7364. For all other issues call 410-786-1326.)

4. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Part D Reporting Requirements; Use:

Title I, Part 423, §423.514 describes CMS’ regulatory authority to establish reporting

requirements for Part D sponsors. It is noted that each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics in the following areas: the cost of its operations; the patterns of utilization of its services; the availability, accessibility, and acceptability of its services; information demonstrating that the Part D plan sponsor has a fiscally sound operation; and other matters that CMS may require. CMS has identified the appropriate data needed to effectively monitor plan performance. Changes to the currently approved data collection instrument reflect new executive orders, legislation, as well as recent changes to Agency policy and guidance. Form Number: CMS–10185 (OCN: 0938–0992); Frequency: Reporting, Recordkeeping and Third-party disclosure; Affected Public: Business and other for-profits; Number of Respondents: 690; Total Annual Responses: 8,067; Total Annual Hours: 12,658. (For policy questions regarding this collection contact Latoyia Grant at 410-786-5434. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by **[OFR—insert date 60 days after date of publication in the Federal Register]**:

1. Electronically. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

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Dated: March 12, 2013

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Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

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